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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/463,874	06/07/00	WANKER E	V0179/7000

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EXAMINER	
TURNER, S	

ART UNIT	PAPER NUMBER
1647	7

DATE MAILED: 09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)	
09/463874	Wanker et al.	
Examiner	Art Unit	
Robert Hayes	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 6/11/01 .

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claim 1-13 (each in part), drawn to a composition comprising a fusion protein comprising (1) a polypeptide that enhances solubility and/or prevents aggregation and (2) an amyloidogenic polypeptide; nucleic acid molecules encoding same; vectors and host cells comprising the nucleic acid molecules; an antibody specific to the fusion protein; or a method of recombinantly expressing the fusion protein.

II. Claim 1-11, 13 (each in part) and 21, drawn to transgenic multicellular organisms that recombinantly express a fusion protein comprising (1) a polypeptide that enhances solubility and/or prevents aggregation and (2) an amyloidogenic polypeptide.

III. Claims 14 and 15, drawn to a method of producing amyloid aggregates in vitro.

IV. Claims 16-19, drawn to a method of testing or identifying inhibitors of aggregate formation.

V. Claim 20, drawn to use of a compound for the preparation of a pharmaceutical

composition for the inhibition of formation of amyloid-like fibrils or protein aggregates.

FURTHERMORE, restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

A. Any of the above inventions, wherein the polypeptide that enhances solubility and/or prevents aggregation is a polyglutamate expansion.

B. Any of the above inventions, wherein the polypeptide that enhances solubility and/or prevents aggregation is GST.

C. Any of the above inventions, wherein the polypeptide that enhances solubility and/or prevents aggregation is intein.

D. Any of the above inventions, wherein the polypeptide that enhances solubility and/or prevents aggregation is thioredoxin.

E. Any of the above inventions, wherein the polypeptide that enhances solubility and/or prevents aggregation is DHFR.

F. Any of the above inventions, wherein the polypeptide that enhances solubility

and/or prevents aggregation is CI2.

FURTHERMORE, restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

1) Any of the above inventions, wherein the amyloidogenic polypeptide is huntingtin.
2) Any of the above inventions, wherein the amyloidogenic polypeptide is androgen receptor.
3) Any of the above inventions, wherein the amyloidogenic polypeptide is atropin.
4) Any of the above inventions, wherein the amyloidogenic polypeptide is TATA binding protein.
5) Any of the above inventions, wherein the amyloidogenic polypeptide is ataxin-1, -2, -3, -6 or –7.
6) Any of the above inventions, wherein the amyloidogenic polypeptide is APP.
7) Any of the above inventions, wherein the amyloidogenic polypeptide is beta-

protein.

8) Any of the above inventions, wherein the amyloidogenic polypeptide is an immunoglobulin light chain.

9) Any of the above inventions, wherein the amyloidogenic polypeptide is serum amyloid A.

10) Any of the above inventions, wherein the amyloidogenic polypeptide is transthyretin.

11) Any of the above inventions, wherein the amyloidogenic polypeptide is cystatin C.

12) Any of the above inventions, wherein the amyloidogenic polypeptide is beta2-microglobulin.

13) Any of the above inventions, wherein the amyloidogenic polypeptide is apolipoprotein A-1.

14) Any of the above inventions, wherein the amyloidogenic polypeptide is gelsoline.

15) Any of the above inventions, wherein the amyloidogenic polypeptide is IAPP.

16) Any of the above inventions, wherein the amyloidogenic polypeptide is calcitonin.

17) Any of the above inventions, wherein the amyloidogenic polypeptide is a prion.

18) Any of the above inventions, wherein the amyloidogenic polypeptide is ANF.

19) Any of the above inventions, wherein the amyloidogenic polypeptide is lysozyme.

20) Any of the above inventions, wherein the amyloidogenic polypeptide is insulin.

21) Any of the above inventions, wherein the amyloidogenic polypeptide is fibrinogen.

22) Any of the above inventions, wherein the amyloidogenic polypeptide is a tau protein.

23) Any of the above inventions, wherein the amyloidogenic polypeptide is alpha-synuclein.

Applicant is advised that one Group must be selected from I-V, one Group must be selected from A-F, **AND** one Group must be selected from 1)-23). **EACH** of I-V, A-F and 1)-23) is a *restriction* requirement, not a species requirement. The restriction was set up in three layers as set forth above, as it was deemed the most concise way of setting forth the restriction, and the most likely

to avoid clerical errors and confusion.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The PCT rules define a special technical feature as a feature which makes a contribution to the prior art. The first claimed invention recites numerous possible compositions recited in the alternative. The existence of any of these compositions in the prior art signifies that the first claimed invention does not make a contribution to the prior art, and thus has no special technical feature as defined by the PCT rules. If the first claimed invention has no special technical feature, the other claimed inventions cannot share a special technical feature with it.

The first claimed invention, in fact, does not have a special technical feature, as it can be found in the prior art. Gutekunst et al. (1995, PNAS USA 92:8710-8714; cited in the PCT written opinion) disclose a fusion protein comprising huntingtin and GST (see p. 8710, second paragraph of right hand column. The huntingtin component inherently has the activity of having the ability to self-assemble into amyloid-like fibrils or protein aggregates; and the GST inherently has the activity of enhancing solubility and/or preventing aggregation.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Hayes, Ph.D., whose telephone number is (703) 305-3132. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

ECK
September 27, 2001